REMARKS OF THE

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TO THE

NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS
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INTRODUCTION

WHEN I ENTERED THE CONGRESS IN 1974, MEDICARE WAS NINE YEARS OLD AND A WELL ESTABLISHED PART OF THE HEALTH CARE SYSTEM. IT WAS A BLESSING FOR THE SICK ELDERLY AND A COMFORT FOR THE WELL.

MEDICARE WAS DOING MUCH GOOD, BUT THE GAPS IN COVERAGE WERE BECOMING PAINFULLY OBVIOUS BY THE MID-1970'S. CONGRESSIONAL CONCERN WAS HIGH, BUT WAS OVERSHADOWED DURING THE CARTER YEARS BY THE DEBATE ON HOSPITAL COST CONTAINMENT AND NATIONAL HEALTH INSURANCE.

IN THE EARLY YEARS OF THE REAGAN ADMINISTRATION, HUGE BUDGET

DEFICITS AND THE PRESIDENT'S AGGRESSIVE ANIMOSITY TOWARD SOCIAL PROGRAMS

STYMIED ALL EFFORTS TO EXPAND MEDICARE.

THE TIME WAS RIGHT

BY THE MID-1980'S, THE STATISTICS ON OUT-OF-POCKET EXPENDITURES BY MEDICARE BENEFICIARIES CLEARLY INDICATED THAT THE PROMISE OF 1965 WAS NO LONGER BEING KEPT. HEALTH PROTECTION FOR THE ELDERLY WAS SLIPPING. THE COSTS OF UNCOVERED SERVICES, LIKE DRUGS, NURSING HOMES AND LONG HOSPITAL STAYS, WERE SKYROCKETING. BENEFICIARIES WERE SCRAMBLING TO BUY PRIVATE, SUPPLEMENTAL POLICIES. EVEN THE REAGAN ADMINISTRATION, WITH ITS BUDGET EYE BLIND TO ALL BUT DEFENSE, COULD NOT IGNORE THE IMPERATIVE TO IMPROVE MEDICARE COVERAGE.

THE ADMINISTRATION CAME FORWARD WITH A PROPOSAL FOR CATASTROPHIC HOSPITAL AND PHYSICIAN COVERAGE. IT WAS GOOD AS FAR AS IT WENT. BUT IT LEFT OUT COVERAGE OF MANY IMPORTANT SERVICES.

IT WAS UP TO CONGRESS TO CONSTRUCT WHAT BECAME THE MEDICARE

CATASTROPHIC COVERAGE ACT OF 1988. AS YOU KNOW, ONE OF THE NEW BENEFITS

WE ADDED WAS OUTPATIENT PRESCRIPTION DRUGS.

THE ELDERLY NEED DRUG COVERAGE

THE ELDERLY USE 30 PERCENT OF ALL PRESCRIPTION DRUGS IN THIS
COUNTRY, AND USE THEM AT ROUGHLY THREE TIMES THE RATE OF THE NON-ELDERLY.

MANY HAVE CHRONIC CONDITIONS THAT REQUIRE THEM TO TAKE EXPENSIVE MEDICATIONS ON A DAILY BASIS TO REMAIN ACTIVE, OR SOMETIMES, ALIVE.

THE MEDICARE CATASTROPHIC LEGISLATION, WITH ITS PRESCRIPTION DRUG PROVISION, REPRESENTS THE MOST SIGNIFICANT IMPROVEMENT IN MEDICARE BENEFITS SINCE 1965. IT IS NOT A MINUTE TOO SOON.

THERE ARE TWO SIMPLE AND COMPELLING REASONS WHY I WANTED TO MAKE COVERAGE OF PRESCRIPTION DRUGS PART OF THE CATASTROPHIC LEGISLATION, AND WHY CONGRESS WAS SUPPORTIVE OF THE NEW BENEFIT. DRUGS ARE ESSENTIAL TO GOOD HEALTH CARE AND, IN THE LAST SEVEN YEARS, THEY HAVE BECOME EXTREMELY EXPENSIVE.

DRUG PRICES

ACCORDING TO THE CONGRESSIONAL BUDGET OFFICE, FIVE AND ONE-HALF MILLION BENEFICIARIES SPEND MORE THAN \$600 A YEAR ON OUTPATIENT PRESCRIPTION DRUGS. TWO MILLION BENEFICIARIES SPEND OVER \$1000 A YEAR. MANY OF THESE BENEFICIARIES HAVE LOW INCOMES; OTHERS ARE ON FIXED INCOMES. NOT ONE OF THEM SHOULD BE LEFT WITH NO PROTECTION AGAINST THE HIGH COST OF ESSENTIAL DRUGS.

IT IS NO WONDER BENEFICIARIES SPEND SO MUCH ON DRUGS. WE ARE IN THE MIDST OF A NEW ERA OF PRESCRIPTION DRUG MARKETING AND PRICING. IT APPEARS THAT BRAND NAME COMPANIES HAVE DECIDED THAT THERE ARE NO LIMITS TO WHAT THEY CAN CHARGE.

THEY CLAIM THEIR PRICE INCREASES ARE JUSTIFIED BY EVER-INCREASING COSTS OF RESEARCH AND DEVELOPMENT. AT THE JULY, 1985 HEARING OF MY SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT ON DRUG PRICE INCREASES, THE DRUG COMPANIES VIGOROUSLY MADE JUST THIS ARGUMENT.

I TOOK THEM AT THEIR WORD AND ASKED THEM FOR PROOF. IN PREPARATION FOR THE SECOND SUBCOMMITTEE HEARING ON DRUG PRICE INCREASES IN APRIL OF 1987, I CONDUCTED A SURVEY OF THE 25 LARGEST RESEARCH-BASED COMPANIES. THEIR COMBINED DRUG SALES REPRESENTED 2/3 OF ALL SALES.

THEIR DATA INDICATED THAT THEIR PRICES HAD RISEN 3 TIMES FASTER THAN NECESSARY TO COVER ALL RESEARCH AND DEVELOPMENT COSTS. FOR THOSE COMPANIES, IN 1982 TO 1986, REVENUES FROM PRICE INCREASES WERE \$4.7 BILLION. REVENUES FROM VOLUME INCREASES AND NEW DRUGS WERE ANOTHER \$4.2 BILLION. DURING THAT SAME TIME PERIOD, THE TOTAL INCREASE IN R AND D COSTS WAS ONLY \$1.6 BILLION.

EVEN WHEN FACED WITH THESE FACTS, THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION PERSISTS WITH THE UNFOUNDED CLAIMS, AND THE COMPANIES WITH THEIR PRICE INCREASES.

HIGH DRUG PRICES DEPRIVE MANY AMERICANS OF ESSENTIAL THERAPY. THE ELDERLY ARE THE HARDEST HIT BECAUSE THEY NEED SO MANY DRUGS. NOW, WITH THIS NEW PREMIUM FUNDED BENEFIT, HIGHER PRICES MEAN HIGHER PREMIUMS WHICH COME STRAIGHT OUT OF THE POCKETS OF THE ELDERLY.

I AM CONFIDENT THE CONGRESS WILL NOT ASK THE ELDERLY TO SUBSIDIZE
THE MULTI-BILLION DOLLAR PROFITS OF DRUG COMPANIES. IF THEIR PRICE HIKES
PERSIST, THERE WILL BE PROMPT CONGRESSIONAL ACTION.

THE NEW DRUG BENEFIT

THE NEW DRUG BENEFIT IS NOT ALL THAT I HOPED FOR. IT WAS SCALED BACK DUE TO CONCERNS OVER THE COST. BUT IT IS A SUBSTANTIAL IMPROVEMENT FOR MEDICARE BENEFICIARIES.

IN ORDER TO ADDRESS COST CONCERNS, WE AGREED TO HAVE THE DRUG BENEFIT PHASED IN. BEGINNING IN JANUARY, 1991, OUTPATIENT PRESCRIPTION DRUGS WILL BE COVERED AFTER A \$600 DEDUCTIBLE IS MET, WITH MEDICARE PAYING 50% OF THE COST.

IN 1992, THE DEDUCTIBLE WILL INCREASE TO \$650, WITH MEDICARE PAYING A 60% SHARE. THE PHASE-IN WILL BE COMPLETED IN 1993 WITH MEDICARE PAYING ITS USUAL 80% AFTER THE DEDUCTIBLE IS MET. FOR 1993, AND EACH SUCCEEDING YEAR, THE DEDUCTIBLE WILL BE SET SO THAT A CONSTANT PROPORTION OF MEDICARE BENEFICIARIES ARE COVERED, OR ABOUT 17 PERCENT.

THE DELAY UNTIL 1991, THE PHASE-IN OF THE CO-PAYMENT, AND LARGE RESERVES WERE INCORPORATED TO GIVE CONGRESS AN OPPORTUNITY TO EVALUATE THE TOTAL COSTS OF THE BENEFIT BEFORE IT IS FULLY IN PLACE. BECAUSE THE DRUG BENEFIT IS FUNDED SOLELY BY PREMIUMS FROM BENEFICIARIES, MANY MEMBERS FEARED THAT UNEXPECTED COST OVERRUNS WOULD PRODUCE MAJOR INCREASES IN PREMIUMS. THE THREE YEAR-PHASE-IN WILL ALLOW TIME FOR MID-COURSE PROGRAM CORRECTIONS THAT SHOULD AVOID PAINFUL PREMIUM HIKES.

THE PROGRAM WILL ESPECIALLY HELP LOW-INCOME MEDICARE BENEFICIARIES.

STATE MEDICAID PROGRAMS WILL COVER ALL PREMIUMS, DEDUCTIBLE AND

COINSURANCE FOR MEDICARE BENEFICIARIES WITH INCOMES BELOW 100% OF POVERTY.

"PARTICIPATING PHARMACIES" WILL BE THE HEART OF THE PROGRAM. THEY
WILL ACCEPT ASSIGNMENT, CHARGE MEDICARE BENEFICIARIES THE SAME FEES AS
OTHER CUSTOMERS, SUBMIT CLAIMS ELECTRONICALLY, AND COUNSEL BENEFICIARIES.

GENERICS WILL BE ENCOURAGED BY MEDICARE. WHEN GENERICS ARE

AVAILABLE, MEDICARE WILL ONLY PAY AT THE GENERIC RATE. TO AVOID THIS

RULE, A DOCTOR MUST WRITE ON THE PRESCRIPTION THAT A BRAND NAME DRUG IS

MEDICALLY NECESSARY.

FUTURE OF DRUG BENEFIT

THE FUTURE OF THE PRESCRIPTION DRUG BENEFIT IS HARD TO PREDICT

BECAUSE IT DOES NOT BEGIN UNTIL 1991. FROM THIS VANTAGE POINT, THOUGH, I

THINK THERE ARE THREE SAFE PREDICTIONS.

FIRST, CONGRESSIONAL CONCERN WITH THE COST OF THE PRESCRIPTION DRUG
BENEFIT WILL CONTINUE UNTIL IT IS FULLY PHASED—IN AND THE COSTS ARE
KNOWN.

THE TREMENDOUS VARIANCE IN THE COST ESTIMATES OF THE CONGRESSIONAL BUDGET OFFICE AND THE DEPARTMENT OF HEALTH AND HUMAN SERVICES WAS A TOPIC OF DISCUSSION THROUGHOUT THE CONFERENCE. WHILE CONGRESS ACCEPTED THE CBO ESTIMATES, SOME COST REDUCING FEATURES WERE INCORPORATED JUST IN CASE THE ADMINISTRATION WAS RIGHT. CONGRESS WILL NOT REST EASY UNTIL EXPERIENCE PROVES US RIGHT.

BALANCING THESE COST CONCERNS IS THE ROCK SOLID SUPPORT FOR THE DRUG BENEFIT. IN MY OPINION, THE PRESCRIPTION DRUG BENEFIT IS THE MOST IMPORTANT ADDITION MADE BY THE CATASTROPHIC LEGISLATION. I BELIEVE THE ELDERLY CONSIDER IT AN ESSENTIAL ADDITION AS WELL.

BECAUSE OF THAT SUPPORT, ANY EFFORT TO ROLL BACK THE CATASTROPHIC LEGISLATION WILL NOT, IN MY OPINION, RESULT IN SIGNIFICANT CHANGES IN DRUG COVERAGE. FRANKLY, I DON'T BELIEVE THOSE CALLING FOR A REVERSAL OF CATASTROPHIC COVERAGE CAN SUCCEED AT ALL. THEY SHOULDN'T.

MY SECOND PREDICTION. WITH THE DRUG BENEFIT WILL COME A NEW AWARENESS AND CONCERN WITH DRUG PRICES.

THROUGH MANY MANDATED REPORTS, THE DEPARTMENT OF HEALTH AND HUMAN SERVICES WILL RECORD, ANALYZE AND EXPLAIN THE IMPACT ON MEDICARE OF DRUG PRICE INCREASES, THE COST OF NEW, HIGH-PRICED DRUGS AND INCREASED PHARMACY CHARGES.

THROUGH A MANDATED ANNUAL GUIDE FOR PHYSICIANS OF PRESCRIPTION DRUG PRICES, PHYSICIANS WILL RECOGNIZE THE FINANCIAL IMPLICATIONS OF THEIR CHOICE OF DRUGS, ESPECIALLY WHEN GENERICS ARE AVAILABLE.

THROUGH REGULAR REPORTS TO CONGRESS FROM THE OFFICE OF TECHNOLOGY

ASSESSMENT AND THE SECRETARY OF HEALTH AND HUMAN SERVICES, CONGRESS WILL

BE PRESENTED WITH THE FACTS BEHIND THE COSTS OF THE DRUG BENEFIT. NO

LONGER WILL THE CASE BE MADE BY IRATE CONSTITUENTS ALONE. PRICE

INCREASES WILL BE RECORDED IN READILY AVAILABLE CONGRESSIONAL REPORTS,

WHICH WILL BECOME PART OF CONGRESSIONAL DEBATE, ESPECIALLY WHEN PREMIUM

INCREASES ARE PERCEIVED TO BE NECESSARY.

THE THIRD SAFE PREDICTION IS THAT WE WILL ENTER A NEW ERA OF INQUIRY ABOUT DRUG USE IN THE ELDERLY.

VOLUMES OF DATA ON DRUG UTILIZATION WILL BE COLLECTED THROUGH THE ELECTRONIC BILLING SYSTEM. THESE DATA WILL ENABLE US TO ANSWER QUESTIONS ABOUT THE QUANTITY AND TYPE OF DRUGS TAKEN BY THE ELDERLY AND ABOUT PHYSICIAN PRESCRIBING PRACTICES.

IT IS SHOCKING HOW LITTLE WE KNOW ABOUT DRUG USE BY THE ELDERLY. AN INVALUABLE WINDFALL FROM THE NEW BENEFIT, AND THE ELECTRONIC BILLING SYSTEM, WILL BE THE ADVANCES IN OUR UNDERSTANDING OF DRUGS AND THE ELDERLY.

IMPLEMENTATION OF DRUG BENEFIT

MANY PEOPLE DREAMED FOR MANY YEARS ABOUT ESTABLISHING A MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT. THE POLITICAL TASK WAS CONSIDERABLE, BUT IT IS ACCOMPLISHED. THERE WERE MANY DIFFICULT DECISIONS IN STRUCTURING THE BENEFIT, BUT THEY ARE MADE.

NOW, THE DIFFICULT JOB IS YOURS. THE HEALTH CARE FINANCING
ADMINISTRATION AND YOU, TOGETHER, MUST IMPLEMENT THE POINT-OF-SALE
ELECTRONIC BILLING SYSTEM, THE ELECTRONIC CLAIMS PROCESSING SYSTEM AND
THE OTHER ADMINISTRATIVE FUNCTIONS THAT ARE ESSENTIAL TO THE SUCCESS OF
THE BENEFIT. I REALIZE THAT WE HAVE ESTABLISHED AN AMBITIOUS SCHEDULE.
BUT I ALSO KNOW THAT YOU AND HCFA ARE PROGRESSING RAPIDLY.

YOUR UNDERTAKING IS EXCITING. YOU ARE ON THE CUTTING EDGE OF TECHNOLOGY. YOUR RESPONSIBILITIES ARE LARGE. MANY MEDICARE BENEFICIARIES AND PHARMACISTS ARE RELYING ON YOU.

THE ADVANCEMENTS IN COMPUTER AND COMMUNICATIONS TECHNOLOGY THAT YOU BRING TO THIS MATTER HAVE, IN SOME WAYS, MADE THIS NEW BENEFIT POSSIBLE. WITH IT, WE CAN OVERCOME THE SIGNIFICANT PROBLEMS OF PROCESSING MILLIONS OF PIECES OF PAPER AND QUICKLY DETERMINING AN INDIVIDUAL'S ELIGIBILITY AND THE AVAILABILITY OF GENERICS.

MEDICARE BENEFICIARIES WILL FOREVER BE THANKFUL THAT THEY DO NOT HAVE TO KEEP DOZENS OF RECEIPTS FOR MONTHS AT A TIME.

THE POINT OF SALE SYSTEM WILL BE QUICK AND EASY. AND FROM A HEALTH STANDPOINT, THE ABILITY TO CONDUCT AN IMMEDIATE CHECK FOR SOME CONTRAINDICATIONS AND ADVERSE REACTIONS IS A MAJOR ADVANCEMENT THAT WILL GREATLY BENEFIT THE ELDERLY.

THE CONGRESS WILL BE MONITORING ANY PROBLEMS THAT DEVELOP AS YOU PROCEED. THE DELAY IN BEGINNING THE BENEFIT IS ALREADY LONG ENOUGH. I AM DETERMINED THAT NO ADMINISTRATIVE ISSUE DELAY US ANY FURTHER.

<u>CLOSING</u>

THE MEDICARE PRESCRIPTION DRUG BENEFIT IS OF DIRECT AND IMMEDIATE

CONCERN TO THE ELDERLY. IT ALSO HAS MAJOR IMPLICATIONS FOR ALL CONSUMERS

OF PRESCRIPTION MEDICINES.

THIS IS THE SECOND MAJOR CHANGE IN THE PHARMACEUTICAL MARKETPLACE SINCE 1984. WITH THE PASSAGE OF THE GENERIC DRUG\PATENT TERM RESTORATION LAW IN 1984, THE CONGRESS ASSURED THE WIDESPREAD AVAILABILITY OF GENERIC DRUGS AND PROVIDED A SIGNIFICANT INCENTIVE FOR GREATER RESEARCH ON NEW DRUGS.

TOGETHER, THESE TWO LAWS ARE CHANGING THE FACE OF THE AMERICAN

PHARMACEUTICAL INDUSTRY. THERE IS A DYNAMIC, NEW GAME IN WHICH ALL THE

OLD RULES ARE RE-WRITTEN.

IN THIS GAME, PRICE MATTERS. MANY MAJOR BRAND NAME COMPANIES SELL GENERICS. GENERIC COMPANIES MAKE NEW DRUGS. SUBSTANTIAL INCREASES IN RESEARCH AND DEVELOPMENT BUDGETS ARE ESSENTIAL FOR BRAND NAME COMPANIES TO SURVIVE.

IN THE NEW GAME, CONSUMERS WILL NEVER LOSE THE BENEFITS OF PRICE COMPETITION FOR OFF-PATENT DRUGS. MEDICARE AND MEDICAID POLICIES WILL DOMINATE THE MARKET AND INFLUENCE PRIVATE INSURANCE AND INSTITUTIONAL PURCHASERS.

BRAND AND GENERIC COMPANIES WITH THE PROPER TALENT AND THE RIGHT MANAGEMENT WILL PROSPER. MOST IMPORTANTLY, THOUGH, THE ELDERLY AND PUBLIC HEALTH ARE THE BIG WINNERS.

I WISH YOU WELL AS YOU UNDERTAKE THIS MOST IMPORTANT TASK.